

4. OPERATIONS

The operations for the field study in Phase I differed considerably from those for the mail-telephone study in Phase II. The operations for each phase are discussed in separate sections below.

4.1 Phase I

The operational components of Phase I consisted of a staged series of processes and procedural steps. The principal stages were:

- Advance mailing to the laboratories;
- Telephone enrollment of laboratories into the study;
- Mailing of a confirmation letter to enrolled laboratories;
- Assignment of each laboratory to a specific field tabulator;
- Transmittal of electronic and hard-copy laboratory contact information from the home office to the tabulator assigned in the field;
- Field tabulator's preliminary telephone contact with the assigned laboratory;
- Field tabulator's visit to the assigned laboratories;
- On-site tour of the laboratory;
- On-site tabulation of test volumes using the Tabulation Device;
- Electronic transmittal of tabulated data from Tabulation Device to the home office computer;
- Transmittal of related hard-copy materials from the tabulator to the home office; and
- Receipt and review of transmitted data and materials by home office management and technical staff.

In addition to this operational main line, there were several general components operations of Phase I These included:

- Assigning and training telephone enrollment staff;
- Recruiting and training the field tabulators;
- Managing and monitoring the telephone enrollment and field tabulation;
- Providing ongoing informational support to personnel at the laboratories through a dedicated toll-free NICLTS laboratory hot line; and
- Providing ongoing technical support to the field tabulators through a dedicated NICLTS tabulator technical support line.

Finally, two quality assurance processes were incorporated into the Phase I operations are described in Section 6. 1, which specifically addresses NICLTS quality control:

- Telephone verification - telephone followup with each tabulated laboratory by home office staff, to verify that the tabulator visited the laboratory and performed the data tabulation in conformity with the protocol and
- Field validation - independent retabulation of a small sample of laboratories by a field tabulator other than the one who performed the original tabulation.

For purposes of both efficiency and security, the NICLTS project carried out most of the home office administrative functions of the operations from a single secure field operations room. The operations room was the location of four ongoing functions:

- Printing and assembly of hard-copy materials needed for the various operational stages;
- Distribution of materials to the several operational functions taking place in the telephone center and in the field, tracking of distributed materials, and receipt of materials from telephone and field operations;
- Permanent filing of all paper records and reports created for the project; and
- Operation of a technical support line for field tabulators.

The following sections describe the important aspects of these components. Section 4.1.1 describes the advance mailing. Section 4.1.2 covers the telephone enrollment. The confirmation letter is described in Section 4.1.3. Details about various field operations components appear 'in Section 4.1.4. Section 4.1.5 deals with the

specific protocol and procedures employed by the tabulator when in the laboratory. The computerized Survey Management System is described in Section 4.1.6. A brief description of the technical support lines appears in Section 4.1.7.

4.1.1 Advance Mailing

The initial contact with each selected laboratory commenced with the mailing of an advance notification letter from Edward L. Baker, Jr., Assistant Surgeon General and Director, Public Health Practice Program Office, CDC. This letter covered the following points:

- Informed the laboratories about the study and its purpose;
- Notified them that they had been randomly selected for the study;
- Stressed the importance of their participation;
- Informed them that the study was authorized under Section 306 of the Public Health Service (PHS) Act (42 USC 242k);
- Assured them that the information they provided would be held in strict confidence in accordance with Section 308(d) of the PHS Act (42 USC 242m); and
- Alerted them to expect a telephone call from a Westat representative, who would speak to them specifically about their participation.

Thus, this letter was designed to inform, encourage, allay any concerns, and attest to the legitimacy of the study and of Westat's involvement. It was one of the measures implemented for both quality assurance and operational efficiency of the study, especially in terms of the effect it would have on encouraging laboratories to participate and be candid and conscientious in providing data.

4.1.2 Telephone Enrollment

Approximately 1 week after the advance notification letter was mailed, telephone enrollment specialists initiated telephone contact with each sampled laboratory. The principal objective of the contact was to elicit the

laboratory's voluntary participation in the study. The other objectives were to do the following:

- Confirm that the facility with which contact was made was clearly the facility associated in the OSCAR database with the sampled CLIA ID number, or secure the information needed to locate that facility, if not;
- Explicitly confirm the CLIA ID number;
- Find a telephone Enrollment Contact, i.e., a telephone respondent who was knowledgeable about the laboratory and could speak for it authoritatively during the telephone enrollment process;
- Secure the name of the Field Contact, i.e., the laboratory staff person who could serve as the on-site, in-person contact for the field tabulator (if different from the telephone Enrollment Contact);
- Resolve any uncertainty about the exact laboratory name (e.g., changes since CLIA application, more explicit or clearer information than provided on application); and
- Identify any locations (other than the point of initial contact) where the laboratory might do testing under the sampled CLIA ID number.

To achieve these objectives, NICLTS employed a telephone enrollment protocol that consisted of a specifically designed set of forms and materials, procedures, and an enrollment specialist training program.

4.1.2.1 Telephone Enrollment Forms and Materials

The telephone enrollment protocol was built upon the use of four principal forms used to guide and structure the enrollment process. A set of these forms was used for each sampled laboratory.

These were:

Respondent Information Sheet (RIS) - The RIS was a printed form that provided the enrollment specialist with all the relevant data from the OSCAR file: laboratory name, address, phone number, CLIA ID number, and the unique anonymous NICLTS ID number assigned to the sampled laboratory. To further assist the enrollment process, the RIS also contained information about the type of laboratory (e.g., hospital, POL) and the date on which the advance letter was mailed to the laboratory.

Contact Questionnaire - The contact questionnaire was a paper form that consisted of a series of questions and statements that guided the enrollment specialist through the practical steps of confirming

contact with the laboratory named on the RIS and finding the appropriate person to speak to about enrolling the laboratory into the NICLTS study.

Enrollment Questionnaire -The Enrollment Questionnaire was a short paper questionnaire administered to the telephone Enrollment Contact. This questionnaire was the center point of the enrollment protocol, covering enrollment of the laboratory, CLIA ID number verification, identification of additional testing locations, and clarification of explicit laboratory name.

Laboratory Enrollment Form (LEF) - The Laboratory Enrollment Form was a paper form used to record the critical information obtained while administering the Enrollment Questionnaire. The blank recording blocks on the form corresponded to items on the Enrollment Questionnaire. When completed, the LEF contained all the information necessary to assign the case to a field tabulator preparatory to carrying out the site visit. A separate LEF was filled out for each location where a laboratory did testing under the sampled CLIA ID number.

Eligibility Screener - The eligibility screener was a supplementary questionnaire administered by the enrollment specialist when a sampled facility claimed that it was not a laboratory and did no clinical tests. Since many facilities that require a CLIA certificate are not laboratories per se or do not think of themselves as performing traditional clinical tests covered by CLIA, it was necessary to ask qualifying questions and structured probes to determine if the facility did indeed have a CLIA certificate and did do some form of testing during calendar year 1996 that would be subject to CLIA regulations. The original protocol called for the enrollment process to ignore this issue and err on the side of caution, by trying to enroll every facility that was confirmed as one of those sampled via the CLIA ID numbers on the OSCAR database. Early experience showed, however, that more facilities than anticipated were Justifiably claiming that they did no clinical testing in 1996. Following the original protocol would have resulted in considerable wasted effort in the field, as well as unnecessary burden for these nonlaboratory facilities. Thus, in consultation with CDC, the NICLTS project managers modified the protocol to screen out truly ineligible facilities at the point of telephone enrollment.

In addition to these principal forms, a variety of other routine, administrative forms were used, such as a Call Record to keep track of information about what occurred on each telephone call attempt and to schedule and record information for callbacks.

4.1.2.2 Telephone Enrollment Training

To ensure that the enrollment specialists and operations supervisors implemented the enrollment protocol correctly, uniformly, and consistently, the NICLTS project staff prepared and carried out a training program

covering protocol procedures and use of the associated forms. This training consisted of two formats:

- Written documentation and training materials and
- An 8-hour training session.

Written Documentation and Materials

There were several types of written documentation and training materials. Collectively, they served a dual purpose. First, they formally documented the activities and procedures performed by the enrollment specialist as part of the overall telephone enrollment protocol. Second, they served as text book and reference guide for the specialists in learning and carrying out their mission. The chief written materials were:

Enrollment Specialist Interviewer Manual - This manual described the various components and procedures for the laboratory enrollment process and provided a general overview about NICLTS and the role of the enrollment specialist. It gave general descriptions and full itemized details about the purpose, contents, and use of each form in carrying out the laboratory enrollment. A significant portion of the manual was devoted, first, to describing the various situations, problems, and roadblocks the specialists were likely to encounter and, second, to outlining the specific procedures to be followed when each situation was encountered. The combination of the various paper forms, the contact procedures, and the methods for handling respondents' questions and objections were the operational embodiments of the enrollment protocol design. Understanding and correctly implementing these components represented the core activities for fulfilling the enrollment protocol.

Question-by-Question Specifications ("Q-by-Qs") - These specifications, which appeared in appropriate chapters of the Interviewer Manual, presented detailed information about each question or data item in the four main enrollment forms. The specialists consulted the Q-by-Qs whenever they were unsure about how a particular situation or response related to the intent of the question or data item.

Training Session

The enrollment specialists were all experienced in general telephone interviewing techniques and in collecting data from business establishments. The NICLTS telephone enrollment training sessions were designed to familiarize them with the specific protocol for the enrollment of laboratories, give them hands-on practice with

the its operational components, and prepare them for the specific circumstances they might encounter when dealing with clinical laboratories. To this end, the NICLTS staff prepared an 8-hour training session.

The main pedagogical approaches were lectures, short exercises addressing specific forms and techniques, group practice sessions, and paired role plays. The group practice sessions and paired role plays consisted of mock interviews designed to give the trainees hands-on exposure to the specific items and processes involved in using the various forms and procedures of the protocol. These exercises were built around specific scenarios that were designed to gradually expose the trainees to different parts of the protocol, to the specific forms and items, and to specific anticipated situations and problems. The scenarios purposively raised important topics and issues that required the group to look up the solutions in the manual, Q-by-Q's, etc., and to work towards a solution by discussing various options. This approach permitted a common, universal exposure to the same training protocol and allowed the trainer to engage in explanations and group discussions about the issues being covered in the exercise.

4.1.2.3 Telephone Enrollment Operations

The preponderance of the enrollment operations consisted of executing the formal enrollment protocol, as embodied in the questionnaires, forms, material and procedures documented in the enrollment specialist manual. In addition, there were some significant administrative or operational components. These included controlling the sample to ensure statistical validity of the tabulated results, processing the information about the enrolled laboratories, managing and supervising the process, and management reporting.

Project managers used a Survey Management System to control the flow of each sampled laboratory from the point where it was sampled from the OSCAR database, through all the operational stages that led to its final disposition as a sample case that was or was not included in the final survey database. The SMS was also the system that captured the information and produced the output needed to support the operations. In terms of the Telephone Enrollment process, the SMS was used to control the assignment of sampled cases to the enrollment process, produce the RIS's, record the result of the enrollment effort for each sampled case, and capture electronically the operational information collected on the LEF as the final product of the enrollment process.

The NICLTS SMS was designed to support the progressive release of the sampled cases over time, with control available at the level of an individual case, if needed. When the enrollment process ended for each laboratory, the next step was to transmit the completed telephone enrollment materials to the field operations room, record the resulting information in the NICLTS SMS, and file the hard-copy materials. For the enrolled cases, all of the information collected on the paper LEF was entered into an SMS electronic record that mirrored the paper LEF's contents. This information was then used by the SMS in carrying forward future operational processes. For nonenrolled cases, a result code indicating the reason for nonenrollment was recorded in the SMS.

Enrollment Operations Management and Supervision. Under the direction of the NICLTS project managers, a team of telephone interviewing managers and supervisors oversaw the day-to-day telephone enrollment operations. In addition to participating in the design of the enrollment protocol and the enrollment training, their responsibility was to ensure that the enrollment specialists understood and adhered to the enrollment protocol, to observe the implementation of the protocol and make recommendations as needed for modifications, and to identify specific problems and work with project management to address them.

The final role played by the telephone enrollment supervisory staff was an important quality assurance measure. Throughout the telephone enrollment process, and especially at the beginning of the process, the supervisory staff monitored a selection of each specialist's telephone contacts. This silent monitoring was carried out from dedicated monitoring stations that allowed the supervisors to hear the enrollment protocol being administered without the specialists being aware of when they were being observed and without intruding on the conversation between the laboratory representatives and the specialists. This monitoring was designed both to ensure that the specialist followed the protocol and to identify any individual or generic difficulties that might exist in administering the forms or otherwise following the protocol. There were no problems of an individual or generic nature that had implications for the validity of the NICLTS protocol and resulting data. The most important finding of the monitoring activity was to detect the desirability of adding the eligibility screener to the protocol (see Section 4.1.2.1).

4.1.3 Confirmation Letter

Each enrolled laboratory received a personalized confirmation letter from the NICLTS data collection contractor's project director. This letter thanked the laboratory for agreeing to participate; referenced the telephone enrollment call; identified the laboratory location by name and address; and reinforced the information provided during the enrollment call, that a laboratory technician would call in the near future to set an appointment to visit the facility. It also reaffirmed the guarantee of confidentiality and provided a toll-free number to call if the laboratory had any questions about the study in general, the tabulation process, or specific technical matters. The purpose of this letter was to reinforce the enrollment call and to serve as a reminder of the impending visit by the field tabulator.

4.1.4 Field Operations

The NICLTS field operations encompassed all of the activities and processes that occurred during the on-site tabulation at the laboratories. These operations also supported them prior to or during the field period. The primary activities were:

- Preparing administrative and data collection materials for the field tabulation;
- Recruiting the field tabulators;
- Training the field tabulators in the tabulation protocol and operational procedures;
- Managing the field operations;
- Carrying out the tabulation protocol and specific field procedures, including the operation of the Tabulation Device;
- Controlling and tracking laboratory assignments; using the Survey Management System and
- Operating the technical support lines for the field tabulators.

The following sections discuss these topics in detail, except for the Tabulation which was described in Section 3. 1. 1.

4.1.4.1 Materials for Field Operations

The field protocol was based on the use of carefully designed forms to guide and standardize the process of contacting laboratories and preparing for the automated data tabulation during the in-person site visit. For each assigned laboratory, the tabulators received a separate case folder containing a set of paper forms that guided and supported their efforts to tabulate a complete inventory of the laboratory testing during calendar year 1996. The most important paper forms were the following:

Combined Laboratory Information/Call Record Form. The Call Record provided the laboratory information, such as identification numbers (CLIA ID and NICLTS ID numbers), laboratory name and address, contact name and telephone number. The remainder of the form served as a log to record each call and contact with the laboratory.

NICLTS Protocol Appointment Form. The tabulator used the Appointment Form to structure the process of contacting the laboratory by telephone. This contact script stated the purpose of the study and provided a sequence of questions and statements to contact the most appropriate respondent. Using this script, the tabulator would learn what kinds of records were available for the later on-site data tabulation and the extent of the test menu.

NICLTS On-Site Protocol. The On-Site Protocol guided the tabulator through each step of the on-site field procedures beginning with the verification of the CLIA ID number, address information and identification of other locations that were associated with the same CLIA ID number. The next step was to introduce the tour of the laboratory to establish the kinds of tests that were performed during calendar year 1996. As the last step before electronically tabulating the data, the On-Site Protocol provided guidance on how to obtain complete test volume information.

Laboratory Tour Form. The Laboratory Tour Form was used in conjunction with the On-Site Protocol to list on a paper spreadsheet detailed information about tests that were performed in calendar year 1996, such as test systems (including manufacturer model number), analytes and specimens. The form also served as a record to identify and distinguish backup systems and quality controls.

List of Waived and PPM Tests. The purpose of showing the list of waived and PPM Tests to each respondent during the laboratory tour was to ensure that all laboratory testing for calendar year 1996 was included in the tabulator's inventory. Pilot test experience had revealed a consistent pattern of laboratories overlooking simpler tests in enumerating the tests that they performed.

Volume Estimation Script. The Volume Estimation Script standardized the steps a respondent needed to take to provide test volume estimates when written or electronic records were unavailable or inaccessible.

Volume Estimation Form. The tabulator used the Volume Estimation Form to record the volume estimates a respondent derived by following the Volume Estimation Script for each analyte-test system-specimen triple.

Tabulation Problem Sheet. The Tabulation Problem Sheet provided space to describe any problem encountered either during the preparation for or during the actual data tabulation using the data Tabulation Device.

4.1.4.2 Field Tabulator Recruitment

A pilot study confirmed the existing belief that the best people for completing the inventory are those who speak the language of the laboratory and who have generalist laboratory technology experience. In addition, the project needed to hire people who could travel overnight from their home locations, who were comfortable around computers, and who had demonstrated interpersonal skills. Based on these needs, Westat advertised nationwide for medical technologists with the following major qualifications:

- Bachelor's degree;
- Current certification or registration;
- 2+ years of clinical laboratory experience;
- Laboratory generalist experience preferred;
- Good interpersonal skills; and
- Interviewing skills or field research a plus.

Nearly 300 candidates responded nationwide. Resumes were reviewed and ranked according to geographic need and then according to the desired characteristics and candidates' availability to attend a training session in January 1997.

Westat considered interviewing candidates in person either by flying them into the Washington, DC area or by having candidates fly to central locations, but these options were ruled out because of the expense involved. A telephone recruitment form was designed to screen candidates over the phone.

As a result of this screening procedure, some candidates were eliminated and the remaining were again ranked according to both technical and interpersonal skills. Those marked highest within targeted geographic regions passed to a reference check. Candidates passing the screening procedure and the reference checks were invited to the field tabulator training course in Bethesda, Maryland.

4.1.4.3 Field Tabulator Training

- During the training program, which took place in January 1997, the tabulators learned the following:
- The background of and necessity for the inventory;
- How to operate the laptop computer with its sophisticated Tabulation Device for recording data;
- How to operate the modem for data transmission;
- The expanded Complexity Model database;
- The tabulation protocol; and
- Administrative details such as how to complete a time and expense form.

Westat prepared a training program and materials for use both during the training sessions and later as a reference guide for the tabulators. The agenda was designed to hold the trainees' interest by introducing a variety of topics each day. The sessions began with a general overview of CLIA 88 and of the NICLTS project. Next, the trainees were introduced to the laptop computer and the Tabulation Device. By the third day, they were ready for specific information on the process of tabulating. They learned how to count tests and how to follow and complete protocol forms. A simple laboratory practice case was introduced. Instructors played the roles of tabulator and laboratory respondent and trainees began to enter data.

Discussions about the first practice case study followed the next day. Guidelines for reporting from the field were given and trainees received instruction on the e-mail system. More instruction followed on various aspects of the Tabulation Device, including use of time-saving features. Three additional practice cases were presented, providing an opportunity to review the protocol and enter mock data.

Training culminated with a practicum session, during which pairs of tabulators each visited one of several local laboratories that had agreed to serve as practice sites, where they carried out the full on-site protocol and tabulation.

4.1.4.4 Field Operations Management

There were five broad tasks associated with the operational and administrative of the field tabulation:

- Assignment of laboratories to field tabulators;
- Supervision and monitoring of the activities and performance of the field tabulators, including periodic and ad hoc reporting by the field tabulators to the field management;
- Communications between the home office management and the field tabulators;
- Ad hoc technical problem reporting, resolution, and documentation; and
- Administrative control, accounting for assigned cases, and management reports about individual case statuses and summary progress statistics.

Field Tabulator Laboratory Assignments

Once a laboratory was enrolled, the NICLTS field manager assigned it to a specific tabulator. This assignment was done primarily on a geographic basis: laboratories were assigned to the tabulator whose home base was the closest to the laboratory or who was on extended travel to handle all the laboratories in a state or region where there was no resident tabulator. Occasional departures from this practice occurred because of overriding considerations such as workload, restricted laboratory availability, or other issues.

The NICLTS SMS contained a module that allowed the field manager to review all enrolled laboratories that were not yet assigned and to assign one or more laboratories to a tabulator. Once a laboratory was assigned to a tabulator in the SMS system, the system flagged the case as being assigned to the specific tabulator for tracking

and reporting purposes. The case was then electronically dispatched to the tabulator's laptop computer over the NICLTS data communication channel.

Supervision and Monitoring of the Field Tabulators' Activities and Performance

A team of three NICLTS home office managers was assigned to oversee and support the day-to-day work of the field tabulators. These managers, designated as "field monitors," were assigned this responsibility because they were highly experienced in survey field operations and could support a field staff that was highly qualified from a technical standpoint but was not necessarily experienced in the field operations of travelling around the country and collecting information on business premises. However, the strong natural abilities of the recruited medical technologist staff in regard to this latter challenge, combined with the extensive NICLTS training program and the ongoing guidance of the field monitors, resulted in a field operation that ran as smoothly and efficiently as those employing veteran field survey data collectors.

In general, the monitors were responsible for overseeing and supporting the field tabulators' activities. Each monitor was assigned one-third of the tabulators, divided roughly into three geographic regions, East, Central/South, and West. Monitors were responsible for assessing the progress, productivity, and quality of each tabulator's overall effort. To accomplish this, they made use of such tools as:

- Regular half-hour weekly phone conference with each tabulator;
- Review of individual timesheets and expense reports;
- Review of summary time and expense statistics generated for each tabulator and for all tabulators;
- Review of various detailed and summary production reports generated from the NICLTS SMS;
- Regular weekly meeting of all home office field operations staff to discuss overall field progress, problems, and plans and to discuss each tabulator's assignments, production, and problems; and
- Individual discussions with other monitors or technical managers.

The monitoring focused on such issues as whether the tabulator was carrying out the field procedures according to plan; was making adequate progress in tabulating the laboratories given the tabulator's caseload and project schedule; and was operating efficiently in use of time, scheduling of appointments, and setting of travel itineraries.

The tabulator review and assessment function of the monitoring process was in itself only a tool to identify individual tabulation or operational processes that were working well or needed improvement, and to identify larger trends that might affect the overall project plan or schedule. The findings resulting from this process then had to be communicated and implemented. The monitors used these findings to provide helpful guidance, useful feedback, and constructive and corrective critiques to individual tabulators. They also used them as the basis for discussion and planning in a weekly field managers meeting and for informing the project director of emerging issues or problems that needed resolution or might dictate a change in procedures, plans, or schedule. For the most part, the individual tabulators and the overall field operations readily met the project plan and the project goals for operational productivity, efficiency, schedule, and product quality. In rare instances the monitors worked with selected individuals to improve their productivity or efficiency or to reinforce the operational procedures after training.

Ad Hoc Technical Problem Reporting, Resolution, and Documentation

The field monitors served as the first point of contact whenever the field tabulators needed to contact the home office with a problem or question. The monitors handled any operational or administrative issues themselves, but documented any other issue on a Problem Resolution Form and referred it to the appropriate technical manager. Complexity Model or clinical issues were referred to the NICLTS clinical managers. Questions about the operation of the Tabulation Device were referred either to the NICLTS field support staff or to the NICLTS systems managers, depending on the nature of the issue. Questions about data communications were referred to the NICLTS systems managers. Questions about laboratory eligibility, CLIA ID numbers, subsampling of daily logs or nursing stations were referred to the NICLTS statisticians. After questions and problems were resolved, the field monitor reported the result back to the tabulator; when appropriate, the resolution was also documented in a formal Field Memo and distributed to all field and home office staff.

A description of the handling of technical problems appears in Section 4. 1.

Field Communications

Because of the operational scope and the technical and operational complexity of the Phase I tabulations, it was essential to maintain several modes and channels of communication for field management purposes.

Field Management Data Communications. NICLTS maintained a data communications link to download assigned cases to the field tabulators' computers and upload tabulated data and case status information from their computers to the home office computer. This communications link was described in Section 3.1.1.4. From a field management standpoint, the key aspect of this system was the regular information it made available to the field managers about the progress of each individual case, each tabulator's caseload, and overall project progress.

Electronic Mail. NICLTS operated an e-mail system for text messages between the field tabulators and the home office that was separate from the data communications channel. Data transmission and text message e-mail links were established through daily (or more frequent) dial-ups from the tabulators' computers to the NICLTS data processing system and the NICLTS e-mail server. The text message e-mail channel allowed two-way communication of electronic memos from home office management to individual tabulators and globally to all tabulators, and from individual tabulators to one or more NICLTS managers in the home office. The e-mails from the home office informed the field staff in writing about general issues or decisions, alerted them to general problems and solutions, and informed them of changes or additions to field operational policies and procedures. E-mails addressed to individual tabulators generally informed them of specific instructions that applied only to their work, answered if specific questions about procedures or individual cases that they had previously communicated to the home office, and alerted them to any specific problems in their own activity or at a laboratory assigned to them.

Voice Communications. As described earlier, each tabulator was assigned to report to a field monitor located in the home office. Each monitor had a dedicated 800-number for her tabulators to call whenever they needed to speak to her, whether for the regularly scheduled weekly call or any other occasion. If the monitor was not available to answer the call, it rolled over in sequence to several other backups, such as to the tabulator

technical support line operated by two individuals during Eastern Time business hours (see Section 4.1.7.2).

Hard-copy Communications. NICLTS used one direct mode of hard-copy communication, a series of nine detailed Field Memos composed by appropriate NICLTS clinical and operations managers. The memos were distributed to the field tabulators weekly for the first month and then as needed. They functioned as a consistent, universal documentation and promulgation of ongoing refinements, elaborations, explanations, and reinforcements of the field protocol and operational procedures.

The commonest and most important topics dealt with the mechanics of the Tabulation Device and explanations of how to handle specific types of tests and analytes within the parameters of the Complexity Model and the tabulation protocol. Other substantive topics were the addition of protocol supplements that put in place operational steps for dealing with CLIA ID number discrepancies and with facilities that claimed not to have done testing in calendar year 1996. The memos also alerted the field staff when new releases (improvements and fixes) of the Tabulation Device software were automatically downloaded to them during the field period and explained what the changes involved. Collectively, the memos constituted a formal supplement to the NICLTS Tabulators Manual.

4.1.5 Field Protocol and Procedures

The field protocol and procedures can be conveniently conceived of as having two logical parts: (1) the on-site protocol that led to the information needed for tabulation and (2) the actual tabulation of the test data.

4.1.5.1 On-Site Protocol

The on-site protocol incorporated all activities associated with the tabulation process. It started with preparation for the visit and ended when all data had been tabulated at a location. Activities on site included confirming the CLIA ID number and touring the laboratory with one of the employees. The tour allowed direct observation of test equipment in use by the laboratory, observation of the testing process, and observation of any equipment that was not associated with any of the recorded tests. It also provided an opportunity to talk with

laboratory personnel. The tabulator asked about current and past use of tests during 1996 and documented the names of the test equipment for later entry into the Tabulation Device.

After completing the tour, the tabulator requested pre-existing volume records. Sometimes these did not exist, particularly in POLs. A special protocol was developed to estimate the volume in these instances.

Finally, with the data sources and the laboratory tour information in hand the tabulator entered all the clusters of analytes, test systems, and biological specimens into the computer.

4.1.5.2 On-Site Tabulation

After touring the laboratory and obtaining testing records, the tabulator used the Tabulation Device to record the data. Upon reaching a site in the laboratory, a tabulator first entered a collection of site details. Data entry then consisted of specifying the following information for each unique cluster encountered:

- Analyte name;
- Biological specimen name;
- Test system name;
- Volume of tests performed in 1996 for the specific combination of analyte, biological specimen, and test system; and
- Number of tests not for patient care that were included in the volume figure.

The system automatically provided the Complexity Model codes for the analyte and the test system as well as the Westat-created code for the biological specimen. Tabulators could also record comments about each test when they considered the information useful for later analyses.

In practice, the analyte name and volume were the only information included in the laboratory's records. Tabulators used information collected during the tour to determine the biological specimen and the test system

associated with each analyte. If necessary, they also asked laboratory personnel to provide additional information.

To ensure that all tests were included when volume data were derived from billing records, they specifically probed to obtain test volume for any test for which there was no charge. When the only available source for the data was tester's estimates, they followed a structured question-and-answer script (see Section 4.1.4.1) to collect the volume data as consistently as possible.

When the tabulator completed work at a site, he or she entered a status code of "Complete" in the Tabulation Device. It then performed a check to ensure that all clusters had associated volume data and reported any problems to the tabulator. If any data problems existed, the system reset the status code to "In Progress." The tabulator could then go back into the data table, correct the problems, and re-enter the "Complete" status code.

4.1.6 Survey Management System Case Management and Reporting

Several sections of this report refer to aspects of the NICLTS Survey Management System, a computerized information system used to manage survey operations. The SMS was at the center of four other data processing/information management systems needed for NICLTS. The systems it intersected with were:

- CDC OSCAR database/NICLTS sampling process, which occupied a front-end position in relation to the SMS;
- Distributed data collection system (field tabulator portable computers with Tabulation Device), which operated in parallel with the SMS;
- Field data communications system, which operated in parallel with the SMS and field data collection system and tied together the data collection, SMS, and data processing systems; and
- Data processing system, which incorporated subsystems for editing, processing, and weighting the tabulated data. The data collection and SMS systems both served as front-end processes to the data processing system, which produced the final weighted database of test volume data.

The SMS covered the functional stages from sample selection to the point where field data tabulation operations had ended and all verification and validation operations had been performed on the tabulated laboratories. The SMS had five primary functions

- **Case Management.** The SMS was first and foremost a process control system that controlled, handled, and accounted for each sampled case at each stage of the process from initial sampling to final disposition of the case at the end of data tabulation operations.⁹
- **Operational Data Processing.** The SMS contained several types of data records where information needed to carry out operations was entered, stored, and updated. These included items such as laboratory names, addressees, and phone numbers, names of people who served as the laboratory contacts for NICLTS, and names of field tabulators.
- **Transaction Processing.** The SMS was based on a structural model that envisioned the NICLTS operations as a series of stages through which each sampled case passed until it reached its end stage. Not every case ended at the same stage, and some cases may not have passed through certain stages. Each time a case moved to a certain stage, or when certain data processing took place on it within a given stage, the act of movement or processing was considered a transaction. Each transaction was recorded in a transaction file within the SMS. This transaction file and associated transaction processing routines that were available to the operations managers constituted the spine of the system that controlled and accounted for each case.
- **Production.** The SMS was a production system, with capabilities to allow data entry, data updates, and output of data onto hard-copy or electronic files needed for field operations or for input to other NICLTS systems.
- **Reporting.** The SMS contained a large number of reports that were available on demand by NICLTS managers. These provided a variety of information at the level of individual cases, individual tabulators, and cumulative summary statistics that enabled the managers to monitor, track, and control the progress of the operations and the movement of specific cases through the transaction process.

⁹ For NICLTS, "case" was defined as the sampled CLIA ID number. Operationally, however, a CLIA ID number could apply to more than one facility. Therefore, within the context of the SMS and field operations, a "case" was defined as the original location associated on the OSCAR database with the CLIA ID number up to the point of enrollment. After enrollment, it was defined as a discrete geographic location where tests were performed under the CLIA ID number. This was the result of the need to account for each such location when tabulating the test data covered by the CLIA ID number, and to send a tabulator to each such location when two or more locations were covered by the same CLIA ID number. (The sampling unit for NICLTS was always the CLIA ID number, and one of the functions of the back-end data processing was to collapse test data collected at multiple operational locations back into a single sample unit CLIA ID number case record.)

4.1.7 Telephone Support Lines

During Phase I, NICLTS operated two toll-free telephone lines for field support purposes. One was the Laboratory Information Line and the other was the tabulator technical support line. Westat home office technical and management staff operated these lines by monitoring and responding to the calls received on them.

4.1.7.1 Laboratory Information Line

The Laboratory Information Line was set up to answer questions from respondents regarding NICLTS. The telephone number was provided to the laboratories at various points in the NICLTS operations. Westat staff monitored the line, responded to queries within one business day, and carried out any needed followup calls until the reason for the call was resolved.

The calls on this line fell into six general categories:

- Requests for additional assurances of the authority for the study and confidentiality of the information collected.
- Requests for clarification of the kinds of records that the tabulator would need for tabulation purposes.
- Information about the process of data collection during the on-site visit, and how long this process would take.
- Updated information about laboratory names, CLIA ID numbers, and locations covered by CLIA ID numbers.
- Leaving messages for field tabulators after they had established contact with the laboratory.
- Occasionally, refusal of a site visit after initial enrollment, owing to a change of heart or subsequent overruling of the original agreement by a higher authority. In most cases, the laboratory representative ultimately agreed to a site visit after speaking to a Westat staff member.

The quality assurance purposes of this line included courtesy to the laboratories, improvement of response rate, improvement of data validity, and logistical support for the laboratories and the field tabulators.

4.1.7.2 Tabulator Technical Support Line

The tabulator technical support line was set up to answer technical questions and solve problems from data tabulators in the field. It was designed to provide real-time support for the tabulators if they had a question or problem during the course of performing the on-site visits and tabulating the data. It was answered by a NICLTS medical technologist who was assigned to this task on a dedicated basis. This person was also expert in the functionality and use of the Tabulation Device. When the line was busy or the call occurred outside business hours, a voice mail system was available as backup.

The calls on this line addressed questions and problems in four general categories:

- Computer-related (both hardware and software),
- Complexity Model,
- Statistical, and
- Administrative.

Most questions and problems were solved on the initial phone contact between the tabulator and the home office medical technologist. Occasionally, some needed to be referred to a NICLTS staff member with suitable knowledge or authority to address the issue (such as the project director, senior statistician, or senior systems manager).

Every issue raised on a call, whether resolved on the call or requiring further review and followup, was documented on a Problem Resolution Sheet, which was then routed to senior staff members for review. In addition to resolving specific questions or problems, this process identified common problems and their resolutions, often resulting in protocol refinements or computer program changes that were relayed to the field through the various communications channels. The quality assurance purposes of this line included technical and operational support for the field tabulators and improvement of data validity.

4.2 Phase II

The operational components of Phase II consisted of a staged series of processes and procedural steps. The principal stages were:

- Advance mailing to the laboratories;
- Telephone enrollment of laboratories into the study;
- Mailing of a cover letter, Test Inventory Form, and Test System Reference List to enrolled laboratories;
- Assembly and transmittal of hard-copy laboratory case folders (contact information and Data Tabulation Form) to the telephone data collection facility;
- Telephone tabulator's collection of test volumes using the Data Tabulation Form;
- Key entry of tabulated data from Data Tabulation Form;
- Transmittal of hard-copy laboratory case folders to field operations room;
- Receipt of transmitted case folders in field operations room; and
- Receipt of hard-copy Data Tabulation Forms in field operations room after key entry.

In addition to this operational main line, there were several general components to the operations of Phase II. These included:

- Assigning and training telephone enrollment staff;
- Recruiting and training the telephone tabulators;
- Managing and monitoring the telephone enrollment and tabulation; and
- Providing ongoing informational support to personnel at the laboratories through a dedicated toll-free NICLTS laboratory hot line.

Finally, two quality assurance processes were incorporated into the Phase II operations and are described in Section 6.2 of this report:

- Monitoring of telephone tabulators: live monitoring of the data tabulation calls by NICLTS supervisory medical technologists and

- Field validation: independent on-site retabulation of a small sample of laboratories by a small group of field tabulators using the same paper Data Tabulation Form used by the telephone tabulators and a special On-site Protocol.

For efficiency and security, the NICLTS project carried out most of the administrative functions of the operations from the same secure field operations room used for Phase I. The operations room was the location where three ongoing functions took place:

- Printing and assembly of hard-copy materials needed for the various operational stages;
- Distribution of materials to the several operational functions in the telephone center, tracking of distributed materials, and receipt of materials back from telephone and key entry operations; and
- Permanent filing of all paper records and reports created for the project.

Except for the natural differences attributable to the use of a mail-telephone methodology to tabulate the test data, the Phase II operations were similar to those for Phase I. For the sake of clarity and brevity, the remainder of Section 4.2 describes only the aspects that are unique to Phase II or significantly different from the analogous Phase I element. Except where operational differences require a different organization, this section parallels that for Phase I and indicates where the description for Phase I applies to Phase II.

4.2.1 Advance Mailing

The advance mailing process for Phase II was identical to that for Phase I.

4.2.2 Telephone Enrollment

The telephone enrollment process for Phase II was nearly identical to that for Phase I. The only significant difference was that the laboratories were requested to respond to mail-telephone data collection rather than to allow a tabulator to visit.

4.2.2.1 Telephone Enrollment Forms and Materials

The telephone enrollment forms and materials were nearly identical to those used for Phase 1. The major differences were:

Contact Questionnaire/Eligibility Screener. The eligibility screening questions were formally incorporated into the normal flow of the contact questionnaire, rather than being a stand-alone supplement as in Phase I.

Enrollment Questionnaire. The wording of relevant items was changed to reflect the fact that the lab was being requested to participate by mail and telephone, rather than being asked to allow an on-site visit.

Laboratory Enrollment Form. The labeling of contact information was changed to reflect a mail-telephone contact rather than a field contact.

4.2.2.2 Telephone Enrollment Training

The telephone enrollment training for Phase II was nearly identical to that for Phase 1. Minor changes were made to the written documentation and to the specific content of several training exercises, to reflect the slight changes to the enrollment forms, the differing nature of the request for the laboratory to participate by mail and phone, and possible difficulties and solutions associated with enrolling the higher concentration of physician office laboratories.

4.2.2.3 Telephone Enrollment Operations

The Phase II telephone enrollment operations were identical to those used in Phase I.

4.2.3 Mailing Operations

The Phase II data tabulation protocol was a combination of mail and telephone data collection modes. The mail mode was based on a packet of NICLTS test data forms and materials that was sent by name to the mail-telephone contact identified during telephone enrollment at each enrolled laboratory. The contact was instructed in a cover letter to use the enclosed forms as guidance in assembling and recording the test data. The

mailed forms were not the ultimate data collection instruments but intermediate forms that the contact used to report the data to the NICLTS telephone tabulator by telephone. The telephone data collection forms were the ultimate data collection instruments. The mailed forms were not to be mailed back or otherwise physically retrieved for the study.

4.2.3.1 Mailing Materials

The mail component of the data collection protocol was built on the use of one form and three standard documents. These materials were mailed to each sampled laboratory as a single packet and included the following:

Customized Cover Letter. Each enrolled laboratory received a personalized cover letter from the Westat project director thanking the laboratory for agreeing to participate and referencing the telephone enrollment call. It briefly explained the enclosures in the packet and informed the recipient that a laboratory technician would call in the near future to collect the data. It reaffirmed the guarantee of confidentiality and provided a toll-free number to call if the laboratory had any questions about the study in general, the tabulation process, or technical matters. The purpose of this letter was to associate the mail package with the telephone agreement to participate in the study (to minimize any possibility that it would be discarded as a mass mail solicitation or marketing research); alert the contact to expect the telephone tabulator's call to collect the data in a few weeks; and encourage him or her to fill out the test data form before the call.

1996 Test Inventory Form and Customized NICLTS ID Label. The mail inventory form sent to the laboratories was a generic form, printed as an eight-page, 8 ½" x 11", saddlestapled booklet. The outside front cover contained the name of the study; CDC's name; the OMB number and disclosure language; and a unique NICLTS identifier label containing the sampled CLIA ID number, full laboratory name and address information as confirmed during the enrollment call, and the NICLTS ID. The inside front cover contained detailed instructions on how to fill out the form, definitions, and a place to record the laboratory's CLIA ID number. The body of the form contained a checkoff list of waived/PPM analytes, with blank lines to record test systems, specimens, and volumes. Where specimen was defined by the analyte, it was preprinted in the specimen line. The form also contained several open-ended items designed to probe for any tests being performed that were not waived/PPM tests. The toll-free technical assistance number was printed at the bottom of each page.

Test System Reference List. The generic Test System Reference List was an eight-page, 8 ½" x 11", saddle-stapled booklet. It listed all known manufacturers' names and models of test systems used for waived tests in 1996. The systems were grouped under their respective analyte categories, which were numbered and listed in the same sequence as in the 1996 Test Inventory Form. The list was designed to

assist respondents who were unsure of the specific full name of any test system that might have been employed in 1996.

NICLTS Mailing Envelope. The mailing envelope for the mail packet was a 9 ½" x 12 ½" white envelope, printed with the NICLTS name and logo and the NICLTS contractor's return address in the upper left-hand corner. In the lower right-hand corner, a short message and discreet graphic were printed to catch the recipient's eye and clearly differentiate this as a legitimate study and not a mass-mailed solicitation or market research. The NICLTS logo was used to catch the eye of recipients and to tie together the NICLTS package, since it also appeared on the front covers of the 1996 Test Inventory Form and the Test System Reference List.

4.2.3.2 Mailing Operations

The mailing operation was performed daily to maintain a steady flow of cases for the telephone tabulators, and to get the inventory form to the laboratory contact while the memory of the telephone enrollment call was still fresh. Each morning, the field room supervisor entered into the SMS the laboratory information on the LEFs from the laboratories enrolled by telephone the previous day. The operations manager ran the SMS mailing modules and computer mail merges to produce the hard copies of the customized materials. The field room supervisor then assembled the inventory form mail packets and posted them by close of business the same day.

Mailout Handling and Quality Assurance

At the beginning of the mail phase, mail support staff stuffed 2,000 blank NICLTS mailing envelopes with a copy of the generic Test System Reference List. The field room supervisor used these prestuffed envelopes when preparing the mail packets for each laboratory.

For overall quality assurance, the matched sets of customized letters and labels were maintained in identical sequence through each stage of the production process: electronic file output, printing/copying, checking, handling, and rechecking. The field room supervisor removed the first inventory form NICLTS ID label from the printed set of ID labels and affixed it to a blank Test Inventory Form, then affixed the corresponding mailing label to the envelope, and finally inserted the personalized letter and labeled Test Inventory Form into the envelope. This process continued through the mailing materials for all the laboratories in the batch.

After all the mailing packets for the day's batch were prepared, the field room supervisor reexamined each prepared set to ensure that the same NICLTS ID appeared on the letter, the Test Inventory Form ID label, and the mailing label. The supervisor counted the packets and verified the count against the control total on the mailing batch report.

4.2.4 Telephone Data Collection

The NICLTS telephone data collection operations encompassed the following primary components:

- Administrative and data collection materials for the telephone tabulation;
- Recruitment of the telephone tabulators;
- Training the telephone tabulators in the tabulation protocol and operational procedures;
- Tabulation protocol and specific telephone procedures, including the use of the Data Tabulation Form;
- Management of the telephone operations;
- Problem resolution; and
- Control and tracking of laboratory assignments.

The following sections discuss these components in detail. Section 4.2.4.1 describes the telephone data collection materials. Sections 4.2.4.2 and 4.2.4.3 describe the recruitment and training of the telephone tabulators. Section 4.2.4.4 presents a detailed explanation of the telephone tabulations operations and management.

4.2.4.1 Telephone Data Collection Materials

The Phase II data collection protocol was based on carefully designed forms us and standardize the process of contacting laboratories and tabulating the data by telephone.

For each assigned laboratory, the telephone tabulators received a separate laboratory casefolder containing the following forms:

Call Record. The Call Record was a combined laboratory information and call record form that was identical to the Call Record for the Phase I field tabulation. It provided the laboratory information, such as identification numbers (CLIA ID number and NICLTS ID) laboratory name and address, and contact name and telephone number. The remainder of the form served as a log to record each call to the laboratory and the resulting information.

NICLTS Telephone Data Tabulation Guide. The Telephone Data Tabulation Guide provided comprehensive guidance to the tabulators for collecting the laboratory test inventory data over the telephone. It contained a scripted protocol that they read aloud to the respondents during the tabulation interview. By explicitly refer-ring to the specific items printed in the mailed 1996 Test Inventory Form, the text in the Telephone Data Tabulation Guide focused the respondent's attention on the completed Test Inventory Form (in the respondent's hand). Each step of the data collection paralleled the steps in the Phase I OnSite Protocol. The guide established the verification of the CLIA ID number confirmed address information, and confirmed enrollment information about other locations associated with the same CLIA ID number.

Once the tabulator began the tabulation of the test data, the parallelism between the Telephone Data Tabulation Guide and the mailed 1996 Test Inventory Form enhanced the data collection process. The second part of the guide contained a numbered list of the waived analytes that was identical to the presentation of these items on the mailed Test Inventory Form. The guide then proceeded to the list of open probes designed to elicit any moderate/high complexity tests the laboratory may have performed, and finally to the open probes about microscopy tests.

NICLTS Telephone Data Tabulation Form. The Telephone Data Tabulation Form was a paper instrument that contained a complete printed list of waived/PPM analytes and the names of the test systems associated with each analyte in the Complexity Model. This list paralleled the list of analytes appearing in the mailed Test Inventory Form and the Telephone Data Tabulation Guide, and also the list of official Complexity Model test system names printed in the mailed Test System Reference List. In the Telephone Data Tabulation Form, each possible test system for a given analyte was listed alphabetically, line by line, below the analyte. Each test system was followed on its line by blank spaces to record specimen, specimen code, and test volume. The Complexity Model code for the test system was preprinted on the line. For any analyte/test system combination that, by definition, could be used for only one specimen, the specimen and specimen code were pre-printed in the space designated for recording these two items.

The Telephone Data Tabulation Form was designed to serve three functions: to support the valid and easy collection of the data from the telephone respondent; to simplify the process of accurately recording the information during the telephone call; and to simplify the accurate entry of data from the Telephone Data Tabulation Form into the NICLTS data file. For ease of use and to ensure the cohesiveness of the data, it was produced as a booklet printed in single-sided, landscape format and comb-bound across the top of the booklet, to allow the tabulator to open it flat on the desk. The three forms-the mailed 1996 Test Inventory

Form, the Telephone Data Tabulation Guide, and the Telephone Data Tabulation Form-paralleled each other precisely and established the controlled linkage among the laboratory respondent, the data collecting tabulator, and the completed test inventory tabulation.

NICLTS Data Collection Problem Form. The NICLTS Data Collection Problem Form was incorporated at the end of the Telephone Data Collection Guide and provided space to describe and flag any technical problems encountered in administering the Telephone Data Tabulation Guide or completing the Telephone Data Tabulation Form.

The telephone tabulators also used the Phase I Volume Estimation Script, which standardized the steps a respondent needed to take to provide test volume estimates when written or electronic records were inaccessible.

4.2.4.2 Telephone Tabulator Recruitment

For Phase II, Westat hired new tabulators living in the Washington, DC area with similar backgrounds and experience to those hired for Phase I. NICLTS supervisory staff interviewed all qualified medical technologists at Westat headquarters and made final selections for training.

4.2.4.3 Telephone Tabulator Training

Training took place at Westat in November 1997 and was similar to that for Phase I. Details relating to computer use were eliminated since the Phase II protocol collected data using paper and pencil. Because the tabulators were local, administrative details regarding expense reporting and travel were also unnecessary.

As in Phase I, there was a formal Tabulator Manual that documented the protocol, forms, and procedures for the telephone tabulation and operations. It included instructions for contacting laboratories and for handling typical contact problems. Since the tabulators had no access to the computerized data Tabulation Device, a second manual contained a hard copy of the expanded Complexity Model database. It also had reference materials, such as the volume estimation protocol and answers to commonly asked questions.

Training sessions used the same training formats as Phase 1: lectures, discussions, hands-on practice, and role plays. Trainees practiced making calls and collecting data through scripted case studies and role plays.

4.2.4.4 Telephone Tabulation Operations and Management

The preponderance of the telephone tabulation operations consisted of executing the formal tabulation protocol as embodied in the forms, materials, and procedures documented in the telephone tabulator manual. There were some additional significant operational and administrative components. As in Phase I, these included controlling of the sample to ensure statistical validity of the tabulated results, processing of the information from the enrolled laboratories and preparing the case folders for data tabulation, management and supervision of the tabulation process, and management reporting.

There were five broad tasks associated with the operation and management of the telephone

- Production of case materials;
- Tabulation procedures;
- Supervision and monitoring of the activities and performance of the telephone tabulators;
- Ad hoc technical problem reporting, resolution, and documentation; and
- Administrative control and accounting for assigned cases and management reports about individual case statuses and summary progress statistics.

Project managers used a Survey Management System similar to that in Phase I to manage the sample and carry out the necessary operational data processing. In terms of the telephone tabulation process, the SMS was used to control the assignment of enrolled cases to the tabulation process, produce the Call Records, and record the result of the tabulation effort for each sampled case.

Production of Case Folders

In advance, the field room supervisor assembled bulk supplies of generic case folders containing blank copies of the materials described in Section 4.2.4.1, except for the Call Record. Each day, after the daily batch of inventory forms was mailed, the field room supervisor used the SMS to produce the laboratory-specific case materials for each laboratory. The supervisor prepared the case folders by affixing a laboratory name and ID label to the outside of a folder and inserting that laboratory's Call Record in the folder. The supervisor prepared all the folders corresponding to each day's mailing batch as a comparable batch ready to be transmitted to the telephone tabulation operations. For quality assurance, after preparing the daily batch, the supervisor checked each completed folder to make sure that all of the materials were present in the folder and that the laboratory-specific materials pertained to the laboratory whose NICLTS ID label and laboratory name label were affixed to the outside of the folder.

After all case folders for the day's batch were prepared, the field room supervisor counted the folders and verified the count against the control total on the mailing batch report. The day's batch of case folders was stored in the NICLTS field operations room and transmitted to the telephone data collection facility 1 week after the date of mailing.

Telephone Tabulation Operations Procedures

The telephone tabulators began calling the laboratories 8 days after the mailing. The primary purpose of the initial call was as a courtesy followup to confirm that the laboratory had received the Inventory Form packet, and to see if the contact had any questions. If the recipient reported that he or she had not received the packet, or if the tabulator spoke with a third party to whom responsibility had been delegated and that person did not have the packet, the tabulator completed a remail request form, which was sent to the operations manager to fulfill the remail request. This early identification of the need to remail a packet or to speak with a new respondent made operations more efficient and reduced the total time it would otherwise have taken to work through the case. Moreover, the laboratories were often ready to provide the data at the time of the courtesy call.

Requesting and Processing Remailing of Inventory Forms to Laboratories

Completed remail request forms were sent to the operations manager to fulfill the remail request. The form allowed for changing the name and address of the mail-telephone contact. Each request was processed the day after the tabulator filled out the request form. The remailing operations were nearly identical to the original mailings, although the two operations were logistically distinct. The only difference was that the standard text for the cover letter in remailings was different from the text for the initial mailing, reflecting that the current mailing was a remailing specifically requested by the current laboratory contact.

Supervision and Monitoring of the Telephone Tabulators' Activities and Performance

Working under the direction of the NICLTS project managers, a NICLTS project medical technologist functioned as the day-to-day telephone tabulation supervisor, with support as needed from other project medical technologist staff. Their responsibility was to ensure that the tabulators understood and adhered to the tabulation protocol, to observe the implementation of the protocol and make recommendations as needed for modifications, and to identify specific problems and work with project management to address them.

The telephone tabulation supervisory staff played an important quality assurance role by monitoring a selection of each tabulator's telephone contacts. This silent monitoring was designed both to ensure that the tabulator followed the protocol and to identify any individual or generic difficulties that might exist in administering the forms or otherwise following the protocol. The telephone supervisors used the findings of the call monitoring to provide feedback to specific tabulators on individual issues, and also to provide general advice to the tabulators as a group on ways to correct minor problems in the way they followed the protocol or recorded the data, or to make improvements in their telephone data collection techniques. There were no problems of an individual or generic nature that had implications for the validity of the NICLTS protocol and resulting data. The telephone protocol and Telephone Data Tabulation Form fulfilled the operational and data validity goals of the NICLTS Phase II that they were designed to accomplish.

Ad Hoc Technical Problem Reporting, Resolution, and Documentation

The telephone tabulation supervisor served as the real-time resource for resolving specific questions, including ones about clinical or Complexity Model issues, protocol issues, or telephone operations and calling procedures. Decisions or problem resolution that related to protocol, clinical, or Complexity Model issues affecting individual laboratories were documented on the Data Collection Problem Form in the back of the Telephone Data Tabulation Guide.

Quality Assurance of Completed Hard-copy Tabulation Form and Materials

Throughout the day, the telephone tabulation supervisor carried out a quality assurance check on the case folders of laboratories for which data collection activity had been finished. These checks included both cases that were successfully tabulated and those that were concluded without a tabulation taking place. He reviewed and edited the tabulated cases to ensure:

- Correct and complete administration of and recording on the Telephone Data Tabulation Guide;
- Completed items on the Telephone Data Tabulation Guide corresponding one-to-one to completed items on the Telephone Data Tabulation Form;
- Correct, complete, and legible recording in the Telephone Data Tabulation Form; and
- Correct coding in the Telephone Data Tabulation Form.

The edit included a thorough review of the Data Collection Problem Form. After editing, the telephone tabulation supervisor confirmed the final status code of all the cases. He then counted the number of actual data lines to be key-entered from the Telephone Data Tabulation Form (i.e., one for each recorded cluster with a non-zero volume) and recorded this count on the front of the form. This count was subsequently key entered along with the volume data and used as a quality control counter to ensure entry of all data.

4.2.5 Survey Management System Case Management and Reporting

The Phase II Survey Management System was a modification of the Phase I SMS and reflected the dropping, adding, or changing of components from Phase I. The principal deletions were modules for assigning cases to individual tabulators and receiving electronic case results from the field. The principal additions were several modules related to the mailing of the Test Inventory Forms to the laboratories and the tracking of hardcopy Telephone Data Tabulation Forms sent to and received from the key entry department. Additionally, a stand-alone SMS was operated for the Phase II field validation component. This SMS was nearly identical to the Phase I SMS.

4.2.6 Laboratory Information and Technical Support Line

During Phase II, NICLTS operated a toll-free telephone line for laboratory support purposes. In contrast to their Phase I counterparts, the Phase II laboratory contacts were personally responsible for the assembly and provision of the 1996 test data. The Test Inventory Form they received and filled out prior to the telephone tabulation call was designed to be clear, simple, and well documented. Nonetheless, it could not anticipate every laboratory situation, and the respondents had to deal with the same kinds of analyte, test system, specimen, and volume counting issues that the field tabulators handled in Phase I. Consequently, the laboratory support line for Phase II performed a combination of the functions performed by the Laboratory Information Line and Tabulator Technical Support Line in Phase I. That is, it provided in a single channel both informational and technical support to the Phase II laboratory respondents.

As in Phase I, Westat home office technical and management staff operated this line by responding to the calls received on it. The telephone number was provided to the laboratories at a variety of points in the NICLTS operations, including at the time of enrollment by telephone, on the cover letter accompanying the mailed Test Inventory Form, on every page of the Test Inventory Form, and by the telephone tabulators as part of the process of making contact and arranging for a convenient time to conduct the telephone data collection. The line was answered by the medical technologist who had functioned as the Phase I Tabulator Technical Support Line operator and the Phase II telephone operations supervisor. When a laboratory respondent could not immediately speak to the medical technologist because the line was busy, the technologist was temporarily busy with other duties, or the call occurred outside of business hours, a voice mail system was available. The medical technologist

responded to voice mail messages as soon as possible (and always in less than one business day); he made any needed followup calls until the reason for the call was resolved.

The calls on this line fell into seven general categories:

- Reports that the CLIA ID number on the mailed Test Inventory Form did not match the CLIA ID number on the certificate, in response to instructions on the Test Inventory Form to report such discrepancies.
- Requests for technical assistance in completing the Test Inventory Form.
- Claims not to be or not to have a laboratory. After (re-)administration of the eligibility screening protocol to such callers, the determination in most cases was that the facility was, in fact, eligible for tabulation.
- General questions regarding confidentiality and the purpose of the study.
- Calls to report the test data, either before or after the telephone contact process began. Even though the instructions on the Test Inventory Form explicitly requested the laboratories not to call to report test data, the telephone tabulation staff always tried to accommodate the caller by determining where in the NICLTS operations system that laboratory's case folder was located and then either conducting the tabulation interview or arranging to call back to collect the data.
- Requests to set a specific, convenient appointment for telephone staff to call to collect the laboratory data. Westat always set the appointment at the caller's request.
- Refusal to participate in the study, subsequent to the initial agreement to participate at the time of the enrollment call.

The quality assurance purposes of this telephone line included courtesy to the laboratories improvement of response rate, improvement of data validity, and technical and logistical support for the laboratories.